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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,485	07/16/2003	Yi Li	PF156D3	7276

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EXAMINER	
STANDLEY, STEVEN H	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,485	LI ET AL.	
	Examiner	Art Unit	
	Steven H. Standley	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to a nucleic acid, and expression vector and a host cell, and method of making the polypeptide, classified in class 536, subclass 23.5.

II. Claims 9 and 16, drawn to a polypeptide and fragments thereof classified in class 530, subclass 395.

III. Claim 10-12, drawn to an antibody, and agonist, or antagonist to the polypeptide of claim 9 classified in class 530, subclass 387.1.

IV. Claim 13, drawn to a method of treating by administration of an agonist of the amine transporter to a patient in need of human amine transporter acitivity, classified in class 514, subclass 1.

V. Claim 14, drawn to a method of treating a patient with the amine transporter gene, classified in class 514, subclass 44.

VI. Claim 15, drawn to a method of treating a patient by inhibiting the amine transporter, classified in class 514, subclass 1.

VII. Claim 17-18, drawn to a method for identifying compounds that bind and compounds that are effective as antagonists or agonists to the amine transporter, classified in class 435, subclass 7.2.

VIII. Claim 19, drawn to a method for diagnosing and analyzing a disease comprising detecting mutations in the nucleic acid, classified in class 435, subclass 6.

IX. Claim 20, drawn to a method for diagnosing and analyzing a disease comprising detecting the polypeptide of claim 9 in a sample derived from a host, classified in class 435, subclass 6.

2. The polypeptide of Invention II is related to the nucleic acids of Invention I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA molecules and proteins are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

3. Inventions I-II and III are drawn to patentably distinct products, wherein each has a different structure and function which require separate searches, and wherein each is capable of separate manufacture and use. Inventions I-II are to a nucleic acid and the polypeptide encoded by it, whereas invention III is to an antibody that binds the polypeptide. Neither of inventions I and II are required for invention III since the antibody can be raised to a fragment of a polypeptide.

4. Inventions I, and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide can be used as a probe for the expression level of the mRNA encoding the protein, instead of in a process of producing a polypeptide (II) or gene therapy (V).

5. Inventions II and III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions II and III are a polypeptide product and an antibody, of which neither can be used in gene therapy, which is the invention of group V.

6. Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons: Group V and groups IV, and VI-IX are directed to methods that are distinct both physically and functionally, and are not required and are not required one for the other. Group V is to a method of treating by gene therapy, while the other methods are directed to methods of treating by administration of agonist or antagonists (IV and VI), methods of identifying compounds (VII), and methods of diagnosing disease (VIII and IX). Therefore, the methods are

directed at different goals and have different steps and are classified differently. Therefore a search and examination of the methods of group V and groups IV, and VI-IX would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

7. Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons: Group IV and groups VI-IX are directed to methods that are distinct both physically and functionally, and are not required and are not required one for the other. Group IV is to a method of treating by administration of an agonist, while the other methods are directed to methods of treating by administration of antagonists (VI), methods of identifying compounds (VII), and methods of diagnosing disease (VIII and IX). Therefore, the methods are directed at different goals and have different steps and are classified differently. Therefore a search and examination of the methods of group IV and VI-IX would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

8. Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons: Group VI and groups VII-IX are directed to methods that are distinct both physically and functionally, and are not

required and are not required one for the other. Group VI is to a method of treating by administration of an antagonist (an inhibitor), while the other methods are directed to methods of identifying compounds (VII), and methods of diagnosing disease (VIII and IX). Therefore, the methods are directed at different goals and have different steps and are classified differently. Therefore a search and examination of the methods of group IV and VI-IX would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

9. Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons: Groups VII-IX are each directed to methods that are distinct both physically and functionally, and are not required and are not required one for the other. Group VII is to a method of identifying compounds and groups VIII and IX are methods of diagnosing disease. Group VIII is a method of diagnosing disease by analyzing nucleic acids, and Group IX is a method of diagnosing disease by analyzing proteins. Therefore these two methods us physically different products. These methods are also directed at different goals and have different steps and in some cases are classified differently. Therefore a search and examination of the methods of group VII-IX together or in any combination would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

10. Inventions I-II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together because inventions I-II are to a nucleic acid and a polypeptide, and in the invention of group IV is a method that uses an antagonist to the polypeptide of invention II. Therefore the inventions cannot be used together. Therefore a search and examination of group I-II and group IV would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

11. Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the product can be practiced with an agonist of any other transporter than the one of the instant application.

12. Inventions I-II and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are products (I-II) and unrelated method (IX). The method of invention IX is a method of diagnosing and analyzing disease comprising

or detecting the level of polypeptide. Neither the nucleic acid of group I nor the polypeptide of group II can be used in the method of detecting the polypeptide.

13. Inventions III and IV, VI and IX are each related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, group III is to a product that is an antibody, an agonist, or an antagonist to the polypeptide, whereas group IV (and VI) is a method of treatment by administering the agonist (or antagonist). The method of administration can be practiced with an agonist or antagonist to a structurally and functionally different transporter. The method of claim IX is a diagnostic method that detects the polypeptide transporter. The product of group III, an antibody, can be used for the method of group IX. However, the method steps of group IX can be practiced with an antibody to HIV protein to detect the disease HIV or AIDS.

14. Inventions I-II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of group VI is a method of treating by administering an inhibitor of the transporter

polypeptide. Neither products of groups I and I are inhibitors of the transporter polypeptide.

15. Inventions I-II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of identifying compounds can be used with a materially different transporter or receptor.

16. Inventions III and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method of group VII can be used to make agonist or antagonist to another transporter or cell surface receptor.

17. Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method steps of group VIII can be used to detect mutations in Factor V Leiden DNA encoding the protein.

18. Inventions II-III and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because invention group VIII is a method of analyzing mutations in nucleic acids. Invention II is a polypeptide and inventions III is an antibody, an agonist, or an antagonist, all of which cannot be used to ascertain mutations in the DNA of invention I encoding the polypeptide of invention II.

Summary

19. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.
8/10/05

LORRAINE SPECTOR
PRIMARY EXAMINER